REMARKS

Reconsideration and allowance of the present patent application based on the following remarks are respectfully requested.

By this Response, claim 63 is newly added. Claims 47, 48, 50-60, and 62 are withdrawn from consideration as being directed to a non-elected invention. Support for newly added claim 63 may be found, for example, on page 22, lines 22-23, of the specification. No new matter has been added. After entry of this Response, claims 35-63 will remain pending in the patent application.

As a preliminary matter, Applicants would like to express appreciation for the courtesies extended to Applicants and Applicants' representatives during the interview with Examiner Oropeza conducted on September 9, 2004.

Claim 62 was withdrawn from consideration as being allegedly directed to a non-elected invention. The election/restrictions requirement is made with traverse.

Claims 35-40, 43, 45, 46, 49 and 61 were rejected under 35 U.S.C. §103(a) based on Dorfmeister *et al.* (U.S. Pat. No. 5,995,868) (hereinafter "Dorfmeister") in view of Mizuno-Matsumoto *et al., IEEE Trans. Biomed. Eng.* 46:3 (March 1999) (hereinafter "the IEEE Article"). The rejection is respectfully traversed.

Claim 35 recites a method of treating a medical disorder comprising, *inter alia*, performing a wavelet cross-correlation analysis on data obtained from the monitoring to determine whether an abnormal state caused by the medical disorder exists. As conceded by the Examiner, Dorfmeister fails to teach or suggest this feature. The Examiner then relied on the IEEE Article as allegedly disclosing wavelet cross-correlation analysis. Applicants respectfully disagree and submit that the IEEE Article does not teach or suggest, alone or in combination with the cited references, a wavelet cross-correlation analysis. As explained during the September 9th Interview with the Examiner, the IEEE Article only discloses the use of three separate methods of analysis, which are (1) an autoregression model, a (2) wavelet analysis, and (3) a cross-correlation analysis. These methods are taught as separate, competing methods for analyzing the same data. In contrast, a wavelet cross-correlation analysis involves two basic steps. First, wavelet transforms are performed on two signals to create wavelet transform functions. The wavelet transforms provide information on the frequency components present in the underlying signals, as well as information on how those frequency components vary over time. (See page 22 of the present application). These wavelet transformed functions are, therefore, two-dimensional functions. ($W_f(a,b)$ where a

and b are the scale and translation parameters, which provide information in the frequency and time domain, respectively). Once the wavelet transforms have been performed on the two signals, the formulae on page 24 of the specification are applied to the two wavelet transformed signals to determine their strengths of correlation. The measurement of the strengths of correlation is expressed by a wavelet cross-correlation function which is also a two-dimensional function. (See top formula on page 24 of the specification – $WC_{x,y}(a,\tau)$). The results of the wavelet cross-correlation analysis are then used in a diagnostic, analytical, or treatment task. The IEEE Article does not use a wavelet cross-correlation analysis. The IEEE Article only discloses the use of cross-correlation functions, which are one dimensional functions, to study the correlation of time signals (which are also one dimensional functions). There is nothing in the IEEE Article that teaches or suggests performing a wavelet cross-correlation analysis. Because the IEEE Article fails to overcome the deficiencies of Dorfmeister, Applicants respectfully submit that any reasonable combination of Dorfmeister and the IEEE Article does not result, in any way, in the invention of claim 35.

Claims 36-40, 43, 45, 46, 49 and 61 are patentable over Dorfmeister, the IEEE Article or a combination thereof by virtue of their dependency from claim 1 and for the additional features recited therein.

Accordingly, reconsideration and withdrawal of the rejection of claims 35-40, 43, 45, 46, 49 and 61 under 35 U.S.C. §103(a) based on Dorfmeister in view of the IEEE Article are respectfully requested.

Claims 41 and 44 were rejected under 35 U.S.C. §103(a) based on Dorfmeister in view of the IEEE Article and further in view of Ward *et al.* (U.S. Pat. No. 5,978,702) (hereinafter "Ward"). The rejection is respectfully traversed.

Claims 41 and 44 depend from claim 35 and are patentable over Dormeister, the IEEE Article or a combination thereof for at least the same reasons provided above related to claim 35 and for the additional features recited therein. Namely, claims 41 and 44 are patentable at least because these claims recite a method of treating a medical disorder comprising, *inter alia*, performing a wavelet cross-correlation analysis on data obtained from the monitoring to determine whether an abnormal state caused by the medical disorder exists.

Ward fails to overcome the deficiency of Dorfmeister or the IEEE Article because Ward is silent about wavelet cross-correlation analysis. Therefore, any reasonable combination of Dorfmeister, the IEEE Article and Ward does not result, in any way, in the invention of claims 41 and 44.

Accordingly, reconsideration and withdrawal of the rejection of claims 41 and 44 under 35 U.S.C. §103(a) based on Dorfmeister in view of the IEEE Article and further in view of Ward are respectfully requested.

Claim 42 was rejected under 35 U.S.C. §103(a) based on Dorfmeister in view of the IEEE Article and further in view of King *et al.* (U.S. Pat. No. 5,925,070) (hereinafter "King"). The rejection is respectfully traversed.

Claim 42 depends from claim 35 and is patentable over Dormeister, the IEEE Article or a combination thereof for at least the same reasons provided above related to claim 35 and for the additional features recited therein. Namely, claim 42 is patentable at least because this claim recites a method of treating a medical disorder comprising, *inter alia*, performing a wavelet cross-correlation analysis on data obtained from the monitoring to determine whether an abnormal state caused by the medical disorder exists.

King fails to overcome the deficiency of Dorfmeister or the IEEE Article because King is silent about wavelet cross-correlation analysis. Therefore, any reasonable combination of Dorfmeister, the IEEE Article and King does not result, in any way, in the invention of claim 42.

Accordingly, reconsideration and withdrawal of the rejection of claim 42 under 35 U.S.C. §103(a) based on Dorfmeister in view of the IEEE Article and further in view of Ward are respectfully requested.

New claim 63 depends from claim 35 and is therefore patentable for at least the same reasons provided above related to claim 35 and for the additional features recited therein.

In view of the foregoing, Applicants respectfully submit that this application is in condition for allowance. A timely notice to that effect is respectfully requested. If any questions relating to patentability remain, the Examiner is invited to contact the undersigned.

Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

LESSER *et al.*

Appln. No.: 09/691,051

Filed: October 19, 2000

Title: TECHNIQUES USING HEAT FLOW MANAGEMENT STIMULATION AND SIGNAL ANALYSIS TO TREAT MEDICAL DISORDERS

Confirmation No.: 5363

Group Art Unit: 3762

Examiner: OROPEZA, FRANCES P.

* * * * *

JOINT DECLARATION OF RONALD P. LESSER, M.D., AND W. ROBERT S. WEBBER, Ph.D., UNDER 37 C.F.R. § 1.132

We, RONALD P. LESSER, M.D. and W. ROBERT S. WEBBER, Ph.D. declare as follows:

1. We are co-inventors of the subject matter claimed in the above-identified U.S. patent application, which is currently being examined by the United States Patent and Trademark Office.

2. Dr. Lesser is presently a Professor of Neurology and Neurosurgery at the Johns Hopkins University School of Medicine in Baltimore, Maryland.

3. Dr. Webber is presently a Research Associate in the Department of Neurology at the Johns Hopkins University School of Medicine in Baltimore, MD.

4. We have both reviewed and are familiar with the contents of the official action dated June 16, 2004. We have also reviewed and are familiar with the references cited by the patent examiner in that official action. We note that the references cited by the patent examiner in the June 16, 2004 official action were also cited in an official action dated November 26, 2003. We have reviewed and are familiar with the November 26, 2003 official action as well.

5. We understand that claims 35-40, 43, 45, 46, 49 and 61 in our patent application are presently rejected as allegedly unpatentable based on U.S. Patent No. 5,995,868, issued to Dorfmeister, *et al.* (hereinafter the "'868 patent"), in view of Mizuno-

Matsumoto *et al.* (IEEE Transactions on Biomedical Engineering. Vol. 46, No. 3, March 1999, "Visualization of Epileptogenic Phenomena Using Cross-Correlation Analysis: Localization of Epileptic Foci and Propagation of Epileptiform Discharges") (hereinafter the "IEEE Article"), that claims 41 and 44 are presently rejected as allegedly unpatentable based on the '868 patent in view of the IEEE Article and further in view of Ward *et al.* (U.S. Patent No. 5978702) (hereinafter the "'702 Patent") and that claim 42 is presently rejected as allegedly unpatentable based on the '868 Patent in view of the IEEE Article and further in view of King *et al.* (U.S. Patent No. 5925070).

6. Each of our presently pending independent claims, *i.e.*, claims 35, 51, 57, and 62, recites "performing a wavelet cross-correlation analysis." We understand that the patent Examiner has maintained the rejection of the claims based on the fact that the IEEE article allegedly discloses wavelet cross-correlation analysis. We disagree with the Examiner and believe that the IEEE Article does not disclose wavelet cross-correlation analysis and would not suggest wavelet cross-correlation analysis to a skilled practitioner, either alone or in combination with other references.

7. The IEEE Article discloses the use of three separate and competing methods of analysis, *i.e.* (1) an autoregressive model (AR Model), (2) a wavelet analysis, and (3) a cross-correlation analysis, for analyzing the same data (See page 272, second column, lines 5-9). The IEEE Article further discloses that these three methods are used separately to analyze Electrocorticographic (ECoG) data of intractable focal epilepsy. (See Abstract of the IEEE Article). However, the IEEE Article does not disclose a wavelet cross-correlation analysis as recited in our claims. For those reasons, we offer the following explanation and comparison of an autoregressive model, a wavelet analysis, a cross-correlation analysis and a wavelet cross-correlation analysis.

8. An autoregressive model is a model wherein values of time series are regressed on one or more previous values. Autoregressive models include linear and nonlinear autoregressive models. In a linear autoregressive model x_k of order P, a time series x_{k-i} is modeled as a linear combination of P earlier values in the time series, with the addition of a correction term e_k. The coefficients a_i ($i=1,\ldots,P$) are fit by minimizing the mean-squared difference between the modeled time series x_k and the observed time series x_{k-i} (or samples). The minimization process results in a system of linear equations for the coefficients a_i. In the IEEE Article, a linear autoregressive model is used to model and to investigate the spectral density of the ECoG signal.

9. A wavelet analysis is a method of analysis that provides information both in the time domain and the frequency spectrum. This method of analysis is used when the time localization of the spectral components is needed. Generally, the wavelet analysis can be used to analyze non-stationary signals, wherein the frequency content changes in time. A wavelet transform of a signal is a two dimensional function, *i.e.* it is a function of two variables, a and b, the scale and translation parameters, respectively. We note that this method is disclosed in paragraph C (page 273) of the IEEE Article.

10. Cross-correlation, on the other hand, works directly with signals in the time domain. It measures the strength of the time domain signal that is common to two input signals being measured. The two input signals may be of different lengths. Cross-correlation also indicates the time delay of the common signal component from one input signal to the other. The cross-correlation output is a function of time in arbitrary units. The cross-correlation is calculated by multiplying the time points of one signal by the time points of the other signal and summing the results to produce one point in the output cross-correlation.

This process is repeated after shifting one time signal one sample point with respect to the other to produce the next point in the cross-correlation output. If the one signal is N samples long and the other is M samples long, the result is N + M -1 samples long. Thus, the output cross-correlation function has more points than the input signals.

11. In contrast to an autoregressive model, a wavelet analysis and a cross-correlation analysis, a wavelet cross-correlation analysis involves two basic steps. First, wavelet transforms are performed on two signals to create wavelet transformed functions. The wavelet transforms provide information on the frequency components present in the underlying signals, as well as information on how those frequency components vary over time. These wavelet transformed functions are, therefore, two-dimensional functions. Once the wavelet transforms have been performed on the two signals, the formulae on page 24 of the specification are applied to the two wavelet transformed signals to determine their strengths of correlation. The measurement of the strengths of correlation is expressed by a wavelet cross-correlation function which is also a two-dimensional function. (See top formula on page 24 of the specification). The results of the wavelet cross-correlation analysis are then used in a diagnostic, analytical, or treatment task.

12. We note that the cross-correlation function $\Phi_{k,i}(\tau)$ (where τ is a time delay in the time domain) shown on page 274 the IEEE Article is a one dimensional function obtained by cross-correlating two time signals $f_k(t)$ and $f_i(t)$. This method of analysis does not provide frequency information. By contrast, the wavelet cross-correlation function $WC_{x,y}(a,\tau)$ (where τ is a time delay in the wavelet space) is a two dimensional function that provides time and frequency information.

13. In summary, autoregressive model, wavelet analysis and cross-correlation analysis are not the same as wavelet cross-correlation analysis.

14. We also declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application, or any patent issuing thereof.

Respectfully submitted,

Ronald P Lesser MD   Date: 15 Sept 04

Ronald P. Lesser, M.D.

W.R.S. Webber   Date: 15 Sept 04

W. Robert S. Webber, Ph.D.

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